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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/038,718 01/02/2002 Paul M. Lizardi 25006.0001U5 4062 10/22/2003 EXAMINER Robert A. Hodges WHISENANT, ETHAN C NEEDLE & ROSENBERG, P.C. ART UNIT The Candler Building, Suite 1200 PAPER NUMBER 127 Peachtree Street, N.E. 1634 Atlanta, GA 30303-1811

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/038,718	LIZARDI, PAUL M.
	Examin r	Art Unit
	Ethan Whisenant, Ph.D.	1634
The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1) Responsive to communication(s) filed on 14 J	<u>uly 2003</u> .	
2a) This action is FINAL . 2b) ☐ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims		
4)⊠ Claim(s) <u>43-50</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>43-50</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9)☐ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>02 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12)☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 		(PTO-413) Paper No(s) Patent Application (PTO-152)

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Non-Final Action

1. The applicant's election of Group I (Claims 1-31) with traverse in the paper filed 15 JUL 03 is acknowledged. It is also noted that Claims 1-42 have been canceled and new Claims 43-50 added. The applicant has traversed the restriction requirement arguing that there is not an undue burden on the examiner to search both groups. The applicant's argument has been fully considered but is not deemed to be persuasive. A *prima facie* case of burden has been shown because the two inventions have acquired a separate status in the art as shown by their different classification. Because the restriction requirement is deemed proper it is herein made **FINAL**. An action on **Claim(s) 43-50** follows.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

DRAWINGS

3. The drawings filed with this application have been approved under 37 CFR 1.84 or 1.152.

NONSTATUTORY DOUBLE PATENTING

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (F d. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- **5.** Claim(s) 43-50 is/are rejected under the judicially created doctrine of double patenting over Claims 1-12 of U. S. Patent No. 6,344,329 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the 329' patent. Although the conflicting claims are not identical they are not patentablly distinct.
- **6.** Claim(s) 43-50 is/are rejected under the judicially created doctrine of double patenting over Claims 1-26 of U. S. Patent No. 6,210,884 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the 884' patent. Although the conflicting claims are not identical they are not patentablly distinct.

REASON FOR ALLOWANCE

7. Besides the double patenting rejections, **Claim(s) 43-50** is/are allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the nucleic acid amplification/detection method(s) recited in Claims 43-50.

CONCLUSION

8. Claim(s) 43-50 is/are rejected and/or objected to for the reason(s) set forth above.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ETHAN WHISENANT PRIMARY EXAMINER